

Aquatic Animal Health Standards Commission Report

USA Comments

October 2008

CHAPTER 1.4.3.

QUALITY AND EVALUATION OF COMPETENT AUTHORITIES

Article 1.4.3.1.

The quality of ~~the~~ *Competent Authorities* depends on multiple factors that include fundamental principles of an ethical, organisational and technical nature. ~~The~~ *Competent Authorities* should conform to these fundamental principles, regardless of the political, economic or social situation of their country.

Compliance with these fundamental principles by the *Competent Authorities* of an OIE Member Country or Territory (Member) is important to the establishment and maintenance of confidence in its *international aquatic animal health certificates* by the *Competent Authorities* of other Members.

These fundamental principles are presented in Article 1.4.3.2. Other factors affecting the quality of *Competent Authorities* are described in the *Aquatic Code* (notification, principles of certification, etc.).

The quality of *Competent Authorities* can be measured through an evaluation, the general principles of which are described in Article 1.4.4.3. and in Article 1.4.4.4.

A procedure for evaluating *Competent Authorities* by OIE experts, on a voluntary basis, is described in Article 1.4.3.5.

Rationale: Syntax

Article 1.4.3.2.

Fundamental principles of quality

The *Competent Authorities* should comply with the following principles to ensure the quality of their activities:

1. Professional judgement

The personnel of *Competent Authorities* should have the relevant qualifications, scientific expertise and experience to give them the ~~competence~~ skills and abilities to make sound professional judgements.

2. Independence

Care should be taken to ensure that *Competent Authorities* personnel are free from any commercial, financial, hierarchical, political or other pressures which might affect their judgement or decisions.

3. Impartiality

~~The~~ *Competent Authorities* should be impartial. In particular, all the parties affected by their activities have a right to expect their services to be delivered under reasonable and non-discriminatory conditions.

4. Integrity

~~The~~ *Competent Authorities* should guarantee that the work of each of their personnel is of a consistently high level of integrity. Any fraud, corruption or falsification should be identified, documented and corrected.

5. Objectivity

~~The~~ *Competent Authorities* should at all times act in an objective, transparent and non-discriminatory manner.

6. General organisation

~~The~~ *Competent Authorities* must be able to demonstrate by means of appropriate legislation or regulations, sufficient financial resources and effective organisation that they are in a position to have control of the establishment and application of *aquatic animal* health measures, and of international *aquatic animal* health certification activities. Legislation or regulations should be suitably flexible to allow for judgements of equivalence and efficient responses to changing situations. In particular, ~~they~~ such legislation should define and document the responsibilities and structure of the organisations in charge of the control of *aquatic animal* movements, *aquatic animal* disease control and reporting systems, epidemiological surveillance and communication of epidemiological information.

A similar demonstration should be made by *Competent Authorities* if they are in charge of veterinary public health activities.

~~The~~ *Competent Authorities* should have at their disposal effective systems for *aquatic animal* disease surveillance, diagnosis and *notification* of disease problems ~~wherever they~~ that may occur in the national territory, in accordance with the provisions of the *Aquatic Code*. They should at all times endeavour to improve their performance in terms of *aquatic animal* health information systems and *aquatic animal* disease control.

The *Competent Authorities* should define and document the responsibilities and structure of the organisation (in particular the chain of command) in charge of issuing *international aquatic animal health certificates*.

Each position within the *Competent Authorities* that has an impact on their quality should be described.

These job descriptions should include the requirements for education, training, technical knowledge and experience.

7. Quality policy

~~The~~ *Competent Authorities* should define and document their policy and objectives for, and commitment to, quality; and should ensure that this policy is understood, implemented and maintained at all levels in the organisation. Where conditions allow, they may implement a quality system corresponding to their areas of activity and appropriate for the type, range and volume of work that they have to perform. The recommendations [in Chapter X.X.X](#) for the quality and evaluation of *Competent Authorities* propose a suitable reference system, which should be used if a Member chooses to adopt a quality system.

8. Procedures and standards

~~The~~ *Competent Authorities* should develop and document appropriate procedures and standards for all providers of relevant activities and associated facilities. These procedures and standards may for example relate to:

- a) programming and management of activities, including international *aquatic animal* health certification activities;
- b) prevention, control and *notification* of disease *outbreaks*;
- c) *risk analysis*, epidemiological *surveillance* and *zoning*;
- d) inspection and sampling techniques;
- e) diagnostic tests for *aquatic animal diseases*;
- f) preparation, production, registration and control of biological products for use in the diagnosis or prevention of *diseases*;
- g) border controls and import regulations;
- h) *disinfection*;
- i) treatments intended to ~~destroy, if appropriate,~~ [prevent, mitigate or eliminate](#) pathogens in *aquatic animal* products.

Where there are standards in this *Code* or in the *Aquatic Manual*, the *Competent Authorities* should comply with these standards when applying *aquatic animal* health measures and when issuing *international aquatic animal health certificates*.

9. Information, complaints and appeals

The *Competent Authorities* should undertake to reply to [legitimate](#) requests from *Competent Authorities* of other Members or any other authority, in particular ensuring that any requests for information, complaints or appeals that ~~they may~~ [are presented](#) are dealt with in a timely manner.

A record should be maintained of all complaints and appeals and of the relevant action taken by

~~the~~ *Competent Authorities*.

10. Documentation

~~The~~ *Competent Authorities* should have at their disposal a reliable and up-to-date documentation system suited to their activities.

11. Self-evaluation

~~The~~ *Competent Authorities* should undertake periodical self-evaluation, especially by documenting achievements against goals, and demonstrating the ~~efficiency~~ effectiveness of their organisational components and resource adequacy.

A procedure for evaluating *Competent Authorities* by OIE experts, on a voluntary basis, is described in Article 1.4.3.5.

12. Communication

Competent Authorities should have effective internal and external systems of communication covering administrative and technical staff and parties affected by their activities.

13. Human and financial resources

Responsible authorities should ensure that adequate resources are made available to implement effectively the above activities.

Rationale:

- Suggested sentence structure and clarifying edits.
- With respect to point 6, *General organization*, while some countries may use the terms “legislation” and “regulations” interchangeably, others do not. We believe the paragraph should be altered to specify “legislation or regulations” to avoid confusion. The examples in this paragraph, such as ‘epidemiological surveillance and communication of epidemiological information’, are not contained in legislation in the United States and in other countries.
- With respect to point 7, *Quality policy*, we appreciate that the intent is to encourage competent authorities to develop policies for highly efficient and effective performance that can be judged against some standard. However, the terms “quality,” “suitable reference system,” and “quality system” are unclear. These terms need to be defined.
- With respect to point 9, *Information, complaints and appeals*, we believe that “legitimate” should be deleted because Competent Authorities should reply to ALL requests from the Competent Authorities of other countries.
- With respect to point 11, *Self-evaluation*, the term “efficiency” should be replaced with the term “effectiveness”. Other countries are not necessarily concerned with the efficiency of the organizational components of the Competent Authorities of the exporting country. The main concern is the effectiveness of the organizational components in providing the information requested by the importing country.

Article 1.4.3.3.

For the purposes of the *Aquatic Code*, every Member should recognise the right of another Member to undertake, or request it to undertake, an evaluation of its *Competent Authorities* where the initiating Member is an actual or a prospective importer of *aquatic animals commodities* and/or where the evaluation is to be a component of a *risk analysis* process that is to be used to determine or review sanitary measures which apply to such trade.

A Member has the right to expect that the evaluation of its *Competent Authorities* will be conducted in an objective and transparent manner. A Member undertaking an evaluation should be able to justify any measure taken as a consequence of its evaluation.

Article 1.4.3.4.

A Member that intends to conduct an evaluation of another Member's *Competent Authorities* should ~~give them~~ provide notice in writing, and allowing sufficient time for the other Member to comply with the request. This notice should define the purpose of the evaluation and details of the information required.

On receipt of a formal request for information to enable an evaluation of its *Competent Authorities* by another Member, and following bilateral agreement of the evaluation process and criteria, a Member should expeditiously provide the ~~other~~ Member requesting the evaluation with meaningful and accurate information of the type requested.

The evaluation process should take into account the fundamental principles and other factors of quality laid down in Article 1.4.3.1. and in Article 1.4.3.2. It should also take into consideration the specific circumstances regarding quality, as described in Article 1.4.3.1., prevailing in the countries concerned.

The outcome of ~~the~~ an evaluation conducted by a Member should be provided in writing as soon as possible, and in any case within 4 months of receipt of the relevant information, to the Member which has undergone the evaluation. The evaluation report should detail any findings that affect trade prospects. The Member that conducts the evaluation should clarify in detail any points of the evaluation on request.

In the event of a dispute between two Members over the conduct or the conclusions of the evaluation of the *Competent Authorities*, the matter should be dealt with in accordance with the procedures set out in Article 1.4.1.3.

Rationale: Suggested changes are edits that provide clarity.

Article 1.4.3.5.

Evaluation facilitated by OIE experts under the auspices of the OIE

The OIE has established procedures for the evaluation of the *Competent Authorities* of Members, upon mutual request by any Members involved in an evaluation.

The OIE International Committee may endorse a list of approved experts to facilitate the evaluation process.

Under these procedures, the Director General of the OIE will recommends an expert~~(s)~~ or experts from that list.

The expert(s) facilitate(s) the evaluation of the *Competent Authorities* of ~~the~~ an individual Member using the OIE *Tool for the Evaluation of Performance of Veterinary Authorities* (OIE PVS Tool), applied as appropriate to the context of the evaluation.

The expert(s) produce(s) a report in consultation with the *Competent Authorities* of the Members involved in a requested evaluation.

The report is submitted to the Director General of the OIE and, with the consent of the Members involved, published by the OIE.

Rationale: Suggested changes are edits that provide clarity.